REMARKS

Claims 1-36 are pending in the application. Claims 22-32 were withdrawn from consideration pursuant to a restriction requirement. Applicant has cancelled claim 5 and amended claim 1. Support for the amendment to claim 1 is found, *inter alia*, in the original claims as filed and in paragraph [0001] of the specification. Applicant has also added new claim 37 that is based on the subject matter of original claim 1 and original claim 6. There is no issue of new matter.

Rejection Under 35 U.S.C. § 112, second paragraph

In the Office Action, the Examiner rejected claims 1-21 and 33-36 as being indefinitely for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner stated that claim 1 discloses a chemical ablation agent in a concentration effective to cause necrosis of said tissue. However, the Examiner states that claim 1 is unclear regarding the terms ablation and necrosis since ablative tissue may present necrosis, but necrosis is not necessarily equivalent to an ablative condition. Further, the Examiner states that it is unclear as to which component of the preamble or the body of claim 1 constitutes the metes and bounds of the invention.

In response, Applicant respectfully traverses the rejection and its accompanying remarks. Applicant agrees with the Examiner's statement that "[t]he word ablation comes from the Latin *ablatum* meaning to carry away" and "necrosis, in contrast, is defined simply as the death of living cells or tissue." The Examiner further states that "[a]blation does not conventionally suggest removal or excision by direct administration of a chemical agent formulation to compromised tissue. Necrosis, on the other hand, may present with portions of necrotized tissue breaking free from compromised region, cycling through the circulatory system. However, this is not ablation in the conventional sense."

Applicant acknowledges the apparent unconventionality of Applicant's invention. Applicant has discovered that the injectable or insertable dosage forms of the present invention that comprises a "chemical ablation agent," when administered in effective amounts, "results in necrosis (death) or shrinkage of nearby tissue upon injection or insertion

of the formulation into the tissue." (paragraph [0015]). The dosage forms of the present invention result in "improved dosage retention in the tissue (e.g., there is little to no back-leakage into the injection tract), thereby improving delivery efficiency of the ablation agents and/or minimizing the adverse effects such as nonspecific tissue damage." (paragraph [0014]). Whereas previous "[c]hemo-ablative approaches...lead[s] to nonspecific ablation of both the prostate as well as surrounding tissues and organs," (paragraph [0004]), the dosage forms of the present invention result in cells subjected to the dosage form to die. For example, paragraphs [0016] to [0019] detail the death of cells, for example, by chemo-ablation agents through osmotic stress, free radical attack, or enzyme digestion.

In addition, to expedite the prosecution of the present application, Applicant has amended the preamble of claim 1 to more distinctly claim the invention. Specifically, claim 1 is directed to an injectable or insertable dosage form for producing specific necrosis of tissue that comes into contact with the tissue. Applicant states that given the amendment to claim 1 and these remarks, Applicant has overcome the rejection under 112, second paragraph and requests that the rejection be withdrawn.

Rejection Under 35 U.S.C. § 112, first paragraph

In the Office Action, the Examiner rejected claims 1-21 and 33-36 under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. Specifically, the Examiner stated that there is no generalized scheme by which to perform that, which is disclosed in subject claim 1, i.e., ablation and necrosis of said tissue. Also, the Examiner states that there is an absence as to how these formulations ablate and/or necrotize tissue.

In response, Applicant respectfully traverses the rejection and its accompanying remarks. Applicant states that the specification provides sufficient teaching to enable one or ordinary skill in the art to make and to use the invention of claim 1. Applicant states that the Examiner has not met his initial burden of establishing a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure).

The Examiner cites Rehman et al., Tissue Chemoablation, (2003), Journal of Endourology, Vol. 17(8):1, to argue that there is unpredictability in the art and that "chemoablation is still very much in the investigational stage for both the prostate and the kidney." However, Applicant respectfully asserts that the fact that the field of chemoablation is still being perfected does not preclude one of ordinary skill in the art from making and using the present invention as claimed. Indeed, the Federal Circuit has stated that to comply with 35 U.S.C. 112, first paragraph, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (an invention directed to a general system to improve the cleaning process for semiconductor wafers was enabled by a disclosure showing improvements in the overall system). Applicant also points out that the cited Rehman et al. article deals with the field of tissue chemo-ablation in general and does not address the field of targeted tissue necrosis, that is, specific necrosis caused by applying a dosage form containing a chemo-ablative agent. The Examiner has not shown otherwise.

In the Office Action, the Examiner also states that that although the specification provides "working examples...by which various dosage forms are compounded and manufactured...there is absence as to how these formulations ablate and/or necrotize tissue."

In response, Applicant states that the specification identifies classes and exemplary chemo-ablative agents for each class and describes how they necrotize tissue. For example, Applicant teaches that when the chemo-ablation agents are "osmotic-stress-generating agents," such as pure salt, osmotic pressure generated will cause cells to "shrivel...[and] die." (paragraph [0016]). When the chemo-ablation agents are free-radical generating agents, the agents form "free radicals in tissue, such as prostate tissue. Upon formation, the free radicals will attack the tissue to create necrosis." (paragraph [0017]).

Thus, Applicant states that the specification contains a teaching of the manner and process of making and using the invention and the Examiner has not provided sufficient reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA

1971)(stating that "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure"). Rehman et al. fails to provide any proof that the chemo-ablating agents do not have the claimed necrotic effect. The Examiner has not provided any other evidence to doubt the presumption of enablement.

Thus, given the remarks above, Applicant respectfully requests the Examiner to reconsider and to withdraw the rejection under 35 U.S.C. 112, first paragraph.

Rejection Under 35 U.S.C. § 103(a)

In the Office Action, claims 1-4, 7-21, and 33-36 are rejected under 35 U.S.C. § 103(a). As evidence of obviousness, the Examiner relies upon U.S. Patent No. 6,905,475 (Hauschild) and U.S. Patent No. 7,015,253 (Escandon), in view of U.S. Patent Nos. 5,469,854 and 5,733,572 (Unger). Claims 5 and 6 were not rejected as obvious over the cited prior art.

In response, Applicants respectfully traverse the rejection but in order to facilitate the prosecution of the application, Applicants have amended independent claim 1 to include the claim limitations of claim 5 (which has been cancelled), which was not rejected as unpatentable over the prior art. Further, Applicant has added new claim 37 which contains the subject matter of original claim 1 and dependent claim 6 (which was also not rejected for obviousness over the prior art). Thus, the claim limitations of claim 5 now appear in each of the pending claims 1-21 and 33-36 and the claim limitations of claim 6 appear in new claim 37.

In light of the amendments, Applicants state that the rejection under 103(a) has been obviated and all outstanding issues have been resolved.

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Examiner Timothy E. Betton
Art Unit 1614

Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicants' attorney at (908) 518-7700 in order that any outstanding issues be resolved.

Respectfully submitted,

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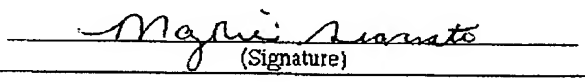

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